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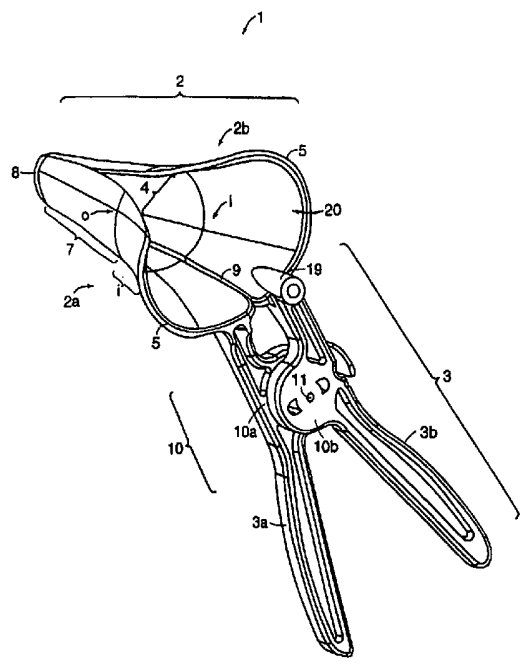
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(54) Title: MEDICAL BODY ACCESS DEVICE

(57) Abstract

A medical device (1) for retracting tissue allows access to the inside of the body by "prying open" an existing or created opening in a body. The device (1) comprises a substantially transparent head (2) having first and second head halves (2a, 2b) defining a substantially conical surface including a gap (4) when the first and second head halves (2a, 2b) are joined. Angular motion of the first and second head halves enlarges the existing or created opening and provides an area of access to the inside of the body. The substantially transparent nature of the device (1) allows it to function as a light pipe so that the operator can see the body cavity or tract opened by the device. The device has scissors-like handles (3) to allow an operator to open or close the device with one hand.



MEDICAL BODY ACCESS DEVICE

Cross-Reference to Related Application

This relates to, and claims the benefit of and priority to, United States provisional
5 application Serial no. 60/082,718, filed on April 23, 1998. The entirety of the disclosure of
that provisional application is hereby incorporated herein by reference.

Technical Field

This invention relates to a medical device that allows access to the inside of the
10 body by "prying open" an existing or created opening in a body.

Background Information

Medical devices for retracting tissue are generally referred to as retractors or
specula. A retractor typically is used to draw aside the edges of a wound or opening (e.g.,
15 to separate and hold open the rib cage of a patient) or to hold back structures adjacent an
operative field. A speculum typically is used to enlarge the opening of any canal or cavity
(e.g., the vagina or the rectum) to facilitate inspection of the interior canal or cavity.

Typically, levers or handles of retractors and specula are disposed in the line of
sight of the body cavity in which the device is inserted thus interfering with an operator's
20 (e.g., a physician's) ability to examine and view the cavity and to properly place medial
instruments into the cavity.

Retractors and specula also typically limit or prevent tactile access. That is, an
operator typically cannot insert a hand or finger into the body opening being held or forced
open by the device.

25 Retractors and specula are typically made of steel, causing discomfort to the
patient. Improper sterilization and repeated use of these instruments also increases risk of
infection.

The reference to any prior art in this specification is not, and should not be taken
as, an acknowledgment or any form of suggestion that that prior art forms part of the
common general knowledge in Australia.



Summary of the Invention

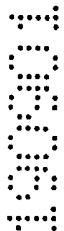
The present invention provides a medical device for retraction, comprising:

a substantially transparent head comprising a first head half, a second head half,
5 and a longitudinal axis, the first head half and the second head half defining a substantially
conical surface including a gap when the first head half and the second head half are
joined; and

a handle coupled to the head, actuation of the handle causing angular motion of the
first head half and the second head half relative to the longitudinal axis, thereby enlarging
10 the gap.

Embodiments of the invention generally relate to a medical retractor/speculum
device for vaginal or other applications that allows access to the inside of the body by
"prying open" an existing or created opening in a body. The device has scissors-like
handles to allow an operator to open or close the

15



device with one hand. In one embodiment of the invention, the device has a locking mechanism to allow the device to stay closed, open, or partially open, as placed by the operator with one hand.

In one embodiment of the invention, a medical device for retracting a body opening
5 comprises a substantially transparent head coupled to a handle. The head comprises a first head half and a second head half which together define a substantially conical surface including a gap when the first head half and second head half are joined. The handle is coupled to the wider base of the head and comprises two handle portions that can be joined at a common hinge or pivot point. The handle portions can be manipulated like the handles of a pair of scissors. Actuation of
10 the handle by bringing the handle portions together causes angular motion of the first head half and the second head half relative to a longitudinal axis of the head, exerting a retraction force on the body opening, thereby enlarging the body opening. Actuation also enlarges the gap in the head so as to provide the operator with an area of access to the inside of the body opening through the gap.

The increase in the size of the gap upon actuation of the handle allows the operator to
15 insert at least a finger, and preferably most of the hand up to the knuckles, into the segment of the head which extends outside of the body opening. This allows the operator the ability to touch the inside of the body opening being retracted and to identify structure(s) within the body opening. As the handle portions can be manipulated with a single hand, the other hand of the operator is
20 free to examine the patient.

In some embodiments of the invention, a longitudinal axis of the handle is substantially
perpendicular to the longitudinal axis of the head, and the handle is disposed out of the line of
sight of the body cavity. Also, the retractor/speculum device can be configured to include a light
source or to receive one or more light-transmitting fibers or cables. The light will illuminate at
25 least the substantially transparent head of the device to provide illumination of the retracted area. The device of the invention allows transvaginal surgical procedures to proceed more quickly and safely than when other known devices are used. One-hand operation of the device is possible, in accordance with the invention.

The foregoing and features and advantages of the invention will become more
30 apparent from the following description, which is by way of example only, and from the claims.



Brief Description of the Drawings

In the drawings, like reference characters generally refer to the same parts throughout the different views. Also, the drawings are not necessarily to scale, emphasis instead generally being placed upon illustrating the principles of the invention.

5 Figures 1A-D show perspective views of a retractor/speculum device in a closed position according to one embodiment of the invention. Figure 1A is perspective view from the top of the device showing the gap formed between the two halves of the head of the device. Figure 1B is a perspective view from the side and back of the device showing the gap formed between the two halves of the head. Figure 1C is perspective view of the back of the device. Figure 1D is a view
10 of the bottom of the head of the retractor/speculum of Figure 1.

 Figures 2A and 2B show perspective views of a retractor/speculum device in an open position according to one embodiment of the invention. Figure 2A is a perspective view from the side and back of the device showing the enlarged gap formed between the two halves of the head of the device. Figure 2B is a perspective view of the back of the device.

15 Figure 3A is a back view of one half of the retractor/speculum of Figure 1. Figure 3B is a perspective view of the half shown in Figure 3A.

 Figure 4A shows the back of a retractor/speculum device according to one embodiment of the invention which includes a locking mechanism. Figure 4B shows an enlarged view of the locking mechanism of the device.

20 Figure 5A shows a perspective view of an embodiment of the invention in which a locking mechanism is provided as part of the hinge assembly of the retractor/speculum device. Figure 5B shows a side view of this embodiment.

 Figures 6A-C show enlarged views of hinge assemblies according to different embodiments of the invention.

25 Figure 7 shows a schematic diagram of the movement of each head half of the retractor/speculum device upon actuation of the handle. The left side of the figure shows the device in a closed configuration. The right side of the figure shows the device in an open configuration.

Description

A device according to the invention is useful for retraction and functions as a medical retractor and/or speculum. As shown in Figures 1A-D, 2A-B, 3A-B, 4A, 5A-B, and 7, the device 1 comprises a head 2 and a handle 3. In a disclosed embodiment, both the head 2 and handle 3
5 comprise two substantially symmetrical halves (first head half 2a and second head half 2b, and handle portions 3a and 3b, respectively) which are generally mirror images of each other. As shown in Figure 7, the two halves 2a and 2b of the head 2 are capable of angular motion relative to a longitudinal axis 23 of the head 2 upon actuation or manipulation of the handle 3, moving away from each other through an arcuate path when the device is being "opened" to exert a
10 retraction force, and moving toward each other when the device is being "closed."

The device 1 can be made of a substantially transparent thermoplastic material that transmits light, such as polycarbonate (e.g., Lexan OQ[®], Flexlite Corporation, Boca Raton, FL), acrylic, or polystyrene, although any type of material that can resist the retraction force of the area being retracted and that can transmit light when illuminated can be used. The device 1 may
15 be entirely substantially transparent or the head 2 alone may be substantially transparent. A substantially transparent material is intended to include any material that can transmit light.

While any type of material can be used that can resist the retraction force of the area being retracted and that can transmit light when illuminated by a light source, plastic has several advantages as a material for the retractor/speculum device 1 (or the head 2 alone) of the
20 invention. As an example, a plastic device 1 is disposable and provides a single-use medical instrument that helps to eliminate the occurrence of cross-infection typically associated with improperly sterilized multi-use metal instruments. Also, because plastic has a lower coefficient of thermal conductivity than steel or metal, the patient experiences less discomfort as the retractor/speculum device 1 of the invention feels warmer and more comfortable to the patient.
25 Moreover, the use of a substantially transparent material, such as clear plastic, results in a device 1 that acts as a light pipe. The need for another operator or assistant to hold a separate light source is eliminated because a light source, or fiber optic lines carrying light from a light source, can be coupled directly to the device 1, to illuminate the substantially transparent portions of the device 1 and thus allow the operator to see the body cavity or tract opened by the device 1.

30 When the device 1 is in a "closed" position and ready to be inserted into a body opening (e.g., as shown in Figures 1A-D, and the left-hand side of Figure 7), the first and second head

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halves **2a** and **2b** define a substantially conical surface with an open base **20**. In the embodiment of the invention shown in Figures 1A-C, 2A, 3B, and 7, the outer surface **o** of the first and second head halves **2a** and **2b** is generally convex and the inner surface **i** of the first and second head halves **2a** and **2b** is generally concave. As used herein, "substantially conical" includes any surface which circumscribes a lumen with a continuously varying internal diameter.

In the embodiment of the invention shown in Figure 1D, each half of the head **2** may be divided into four basic elements which contribute to the head **2**'s substantially conical surface: half of a semicircular ridge **5** which is the point of coupling for one of the handle portions (**3a** or **3b**) of the handle **3** and which forms the base of the conical surface; half of a first frustoconical portion **6** which is proximal to the semicircular ridge **5**; half of a second frustoconical portion **7** adjacent to the first frustoconical portion **6**; and half of a tip portion **8**, located at the distal insertion end of the head portion **2**. The first frustoconical portion **6** is generally wider in radius than the second frustoconical portion **7**. A head half and respective handle portion may be molded as a single piece, being integral with a respective handle portion; alternatively, a head half may be attached or fused to a handle piece which is molded separately.

In a further embodiment of the invention, as shown in Figures 5A and 5B, a discrete semicircular ridge **5** may not be present and the handle portions **3a** and **3b** may be attached directly to the respective halves of frustoconical portion **6**.

When the device **1** is in a closed position, as shown in Figures 1A-D and the left-hand side of Figure 7, the first and second head halves **2a** and **2b** are in close proximity. As shown in Figure 1D, for example, the first head half **2a** and the second head half **2b** contact each other along a midline **9** along the lower surface of the head **2**. In contrast, the upper surface of both the first frustoconical portion **6** and the second frustoconical portion **7** are partially "cut-away" such that when the two halves of the head are in close proximity, the upper surface of the head **2** comprises a gap **4**.

Once in the body opening, actuation of the handle portions **3a** and **3b** of the handle **3** causes the first and second head halves **2a** and **2b** to splay apart (e.g., as shown in Figures 2A and 2B and in the right-hand side of Figure 7), thereby enlarging the body opening. In the "open" or splayed-apart position, the gap **4** in the head **2** enlarges. This enlarged gap **4**, together with opening **20** at the base of the head **2**, provides an area of access that allows the operator to insert one or more fingers into the body cavity and inspect the body cavity tactilely at least near the gap **4**.

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The gap 4 also provides the operator with the ability to insert a variety of medical instruments into the body cavity, for example a suturing mechanism. The device 1 may be opened completely or may be opened to an intermediary position, depending upon the amount of clearance required.

5 The handle 3 of the device 1 comprises two halves, namely, handle portion 3a and 3b. In the embodiment of the invention shown in Figures 1A-C, the two handle portions 3a and 3b join at a hinge assembly 10. As shown in an enlarged view in Figures 6A and 6B, hinge assembly 10 comprises hinge elements 10a and 10b, which are extensions of handle portions 3a and 3b, respectively, and comprise complementary shapes. Hinge elements 10a and 10b are connected at a pivot point 11. The hinge elements 10a and 10b may have coupling elements, such as mating plastic elements 12a and 12b, respectively, that snap together to form the pivot point 11 (Figure 10 6A). Alternatively, the hinge elements 10a and 10b can be joined by a bolt or rod 13 inserted at a hole 14 that runs through each hinge element 10a and 10b (Figure 6B). In this embodiment of the invention, the bolt or rod 13 may be secured by a nut or pin.

In another embodiment of the invention, shown in Figures 2A and 2B, the two handle 15 portions 3a and 3b join at a different type of hinge assembly 15. As shown in the enlarged view of hinge assembly 15 in Figure 6C, one of the handle portions, in this example, 3b, comprises a first and second interconnection element 15u and 15l, while the other handle portion, in this example, 3a, comprises an inner interconnection element 15m. The inner interconnection element 15m is sandwiched, or interleaved, between the first and second outer interconnection elements 20 15u and 15l by a coupling element at pivot point 11. As with hinge assembly 10, discussed above, interconnection elements 15u, 15l, and 15m may be joined together by means of plastic mating elements 12a and 12b (as shown in Figure 6C) or by a bolt or rod.

In the embodiment of the invention shown in Figures 4A and 4B, the handle 3 further 25 comprises a locking mechanism 16. The locking mechanism comprises two sets 16a and 16b of resilient, evenly spaced lugs, each set projecting from the distal ends of first and second cross-bars 17a and 17b, which extend from handle portions 3a and 3b, respectively, in a direction generally perpendicular to the longitudinal axis of the handle 3. Cross-bars 17a and 17b are slightly offset from each other and the lugs at the distal end of one cross-bar point in an opposite direction to the lugs at the distal end of the other cross-bar such that both sets of lugs 16a and 16b can snap 30 together to effectively lock the device. The locking mechanism 16 may be released by the operator applying a twisting action with one hand to the handle portions 3a and 3b thereby

unsnapping the lugs. In a different embodiment of the invention, the operator may release the locking mechanism 16 by pushing down on a thumb tab 18 at the distal end of one of the cross-bars.

In another embodiment of the invention, an integrated locking mechanism/hinge assembly 5 21 is provided. As shown in Figure 5A, one of the handle portions, in this example, 3b, may comprise a mating hinge element 21m which comprises a plurality of projections 21p. The other handle portion, in this example, 3a, comprises an engaging portion 21e, which is capable of meshing with one of the projections 21p of the mating hinge element 21m to lock the device in a selected position. It should be readily apparent to one of ordinary skill in the art that the mating 10 hinge element 21m may be configured to comprise any number and arrangement of projections 21p, so long as the position of the projections 21p relative to the engaging portion 21e changes upon movement of the handle portions, 3a and 3b, to restrict further movement of the handle 3. In one embodiment of the invention, manipulation of the handle portions 3a and 3b with the single hand of an operator can engage this locking mechanism.

15 The orientation of the handle 3 relative to the head 2 of the device 1 may be varied to provide an operator with freer access to a body opening. In the embodiment of the invention shown in Figures 1A-C, 2A-B, 3A-B, 4A, 5A-B, and 7, the handle portions 3a and 3b of the handle 3 are disposed substantially perpendicular to the two halves 2a and 2b, respectively, of the head 2. This arrangement allows the operator to have access to the head 2 and the body cavity in 20 which the head 2 is inserted without interference from the two handle portions 3a and 3b. As defined herein, "substantially perpendicular" refers to an orientation of the handle 3 relative to the head 2 in which the handle 3 is out of the line of sight of the body opening.

The two handle portions 3a and 3b of the handle 3 can also be oriented at other than 90 25 degrees from the two halves 2a and 2b of the head 2. In an alternative embodiment of the invention, the two handle portions 3a and 3b of the handle 3 can be oriented in the same plane as the longitudinal axis 23 of the head 2 to a point on the handle 3 distal to a hinge assembly 10 or 15. The two handle portions 3a and 3b of the handle 3 could then angle downward in a direction away from the opening 20 at the base of the head 2. In the embodiment of the invention shown in Figure 4A, the two handle portions 3a and 3b of the handle 3 have a 30 degree angle of 30 activation.

In another embodiment of the invention, a fixture or socket 19 for receiving one or more light-transmitting fiber optic lines or cables or a light source can be disposed on the semicircular

ridge 5 (or on the rim of frustoconical portion 6 when there is no ridge) of one or both halves 2a and 2b of the head 2. As shown in Figure 1D, the socket(s) 19 can be cylindrical-shaped with a ribbon element 22 that retains the cable(s) or the light source, preferably by a collapsible friction fit. The shape and size of the socket(s) 19 can be complementary to any fiber optic light cable(s) or light source that is known in the art. Also, the socket(s) 19 can be located elsewhere, such as on handle portion 3a and/or 3b. Because of the substantially transparent nature of the device 1, the cable(s) or light source provides a means to illuminate the device 1 and allow the operator to see into the body cavity being retracted without the need for an external light being shined into the body cavity by an individual assisting the operator. In a further embodiment of the invention, when the longitudinal axis of the handle 3 extends substantially perpendicularly from the head 2 of the device 1, only the head 2 of the device 1 need be substantially transparent.

It should be readily apparent to those of ordinary skill in the art that the exact dimensions of the different components of the device 1 can be varied depending on the nature of the opening being retracted. In one embodiment, such as the embodiment shown in Figure 2B, the dimensions of the device 1 can be as follows: L1 can be approximately 8 inches and L2 can be approximately 2 inches. In the embodiment of the invention shown in FIG. 1D, the dimensions of the device 1 can be as follows: L3 can be approximately 1 inch, L4 can be approximately 1 5/8 inches, L5 can be approximately 3 inches, and L6 can be approximately 5 inches

Having thus described certain embodiments of the present invention, various alterations, modifications, and improvements will be apparent to those skilled in the art. Such variations, modifications, and improvements are intended to be within the spirit and scope of the invention. The materials employed, as well as their shapes and dimensions, generally can vary. Accordingly, the foregoing description is by way of example only and is not intended to be limiting.

Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.



Claims

- 1 1. A medical device for retraction, comprising:
2 a substantially transparent head comprising a first head half, a second head half,
3 and a longitudinal axis, the first head half and the second head half defining a
4 substantially conical surface including a gap when the first head half and the second
5 head half are joined; and
6 a handle coupled to the head, actuation of the handle causing angular motion of
7 the first head half and the second head half relative to the longitudinal axis, thereby
8 enlarging the gap.
- 1 2. The medical device of claim 1, wherein the first head half and the second head half
2 comprise a thermoplastic material.
- 1 3. The medical device of claim 2, wherein said thermoplastic material comprises
2 polycarbonate.
- 1 4. The medical device of claim 1, wherein the handle comprises a first handle portion and a
2 second handle portion, the first handle portion coupled to the first head half and the
3 second handle portion coupled to the second head half, the first and second handle
4 portions being joined at a common pivot point.
- 1 5. The medical device of claim 4, wherein the first handle portion is integral with the first
2 head half and the second handle portion is integral with the second head half.
- 1 6. The medical device of claim 4, wherein the first handle portion comprises a first and
2 second outer interconnection element, and the second handle portion comprises an inner
3 interconnection element, the inner interconnection element being sandwiched between the
4 first and second outer interconnection elements and being connected thereto by a
5 coupling element at the pivot point.
- 1 7. The medical device of claim 6, wherein the coupling element comprises a bolt.
- 1 8. The medical device of claim 7, wherein the coupling element comprises two mating
2 plastic elements which snap together.
- 1 9. The medical device of claim 4, wherein at least one of the first and second handle
2 portions includes a socket for receiving a light source.



10. The medical device of claim 9, wherein the socket receives at least one light-transmitting fiber optic line.
11. The medical device of claim 9, wherein the socket receives one or more light-transmitting cables.
12. The medical device of claim 1, wherein the handle includes a locking mechanism.
13. The medical device of claim 1, further comprising a light source for illuminating at least the head.
14. The medical device of claim 13, further comprising one or more sockets for receiving a light source.
15. The medical device of claim 14, wherein at least one of the sockets receives at least one light-transmitting fiber optic line.
16. The medical device of claim 14, wherein at least one of the sockets receives one or more light-transmitting fibers.
17. A medical device substantially as hereinbefore described with reference to the accompanying drawings.

DATED this 19th day of September, 2001

25 **Boston Scientific Limited**

by DAVIES COLLISON CAVE
Patent Attorneys for the Applicant



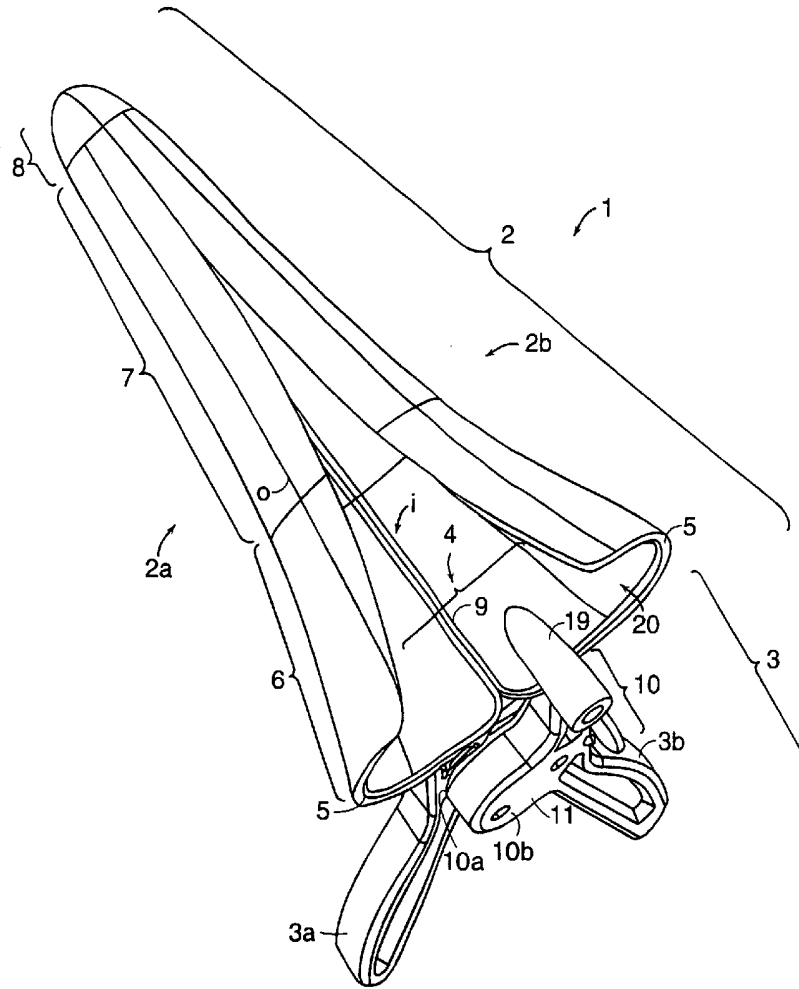


FIG. 1A

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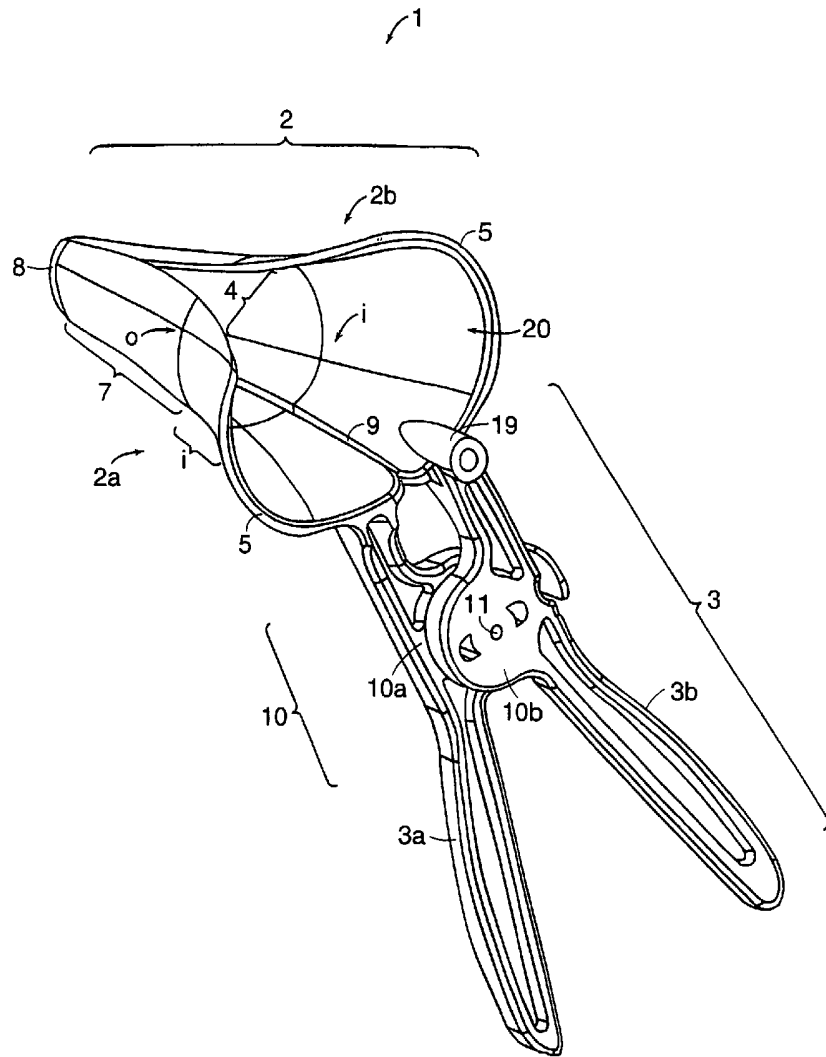


FIG. 1B

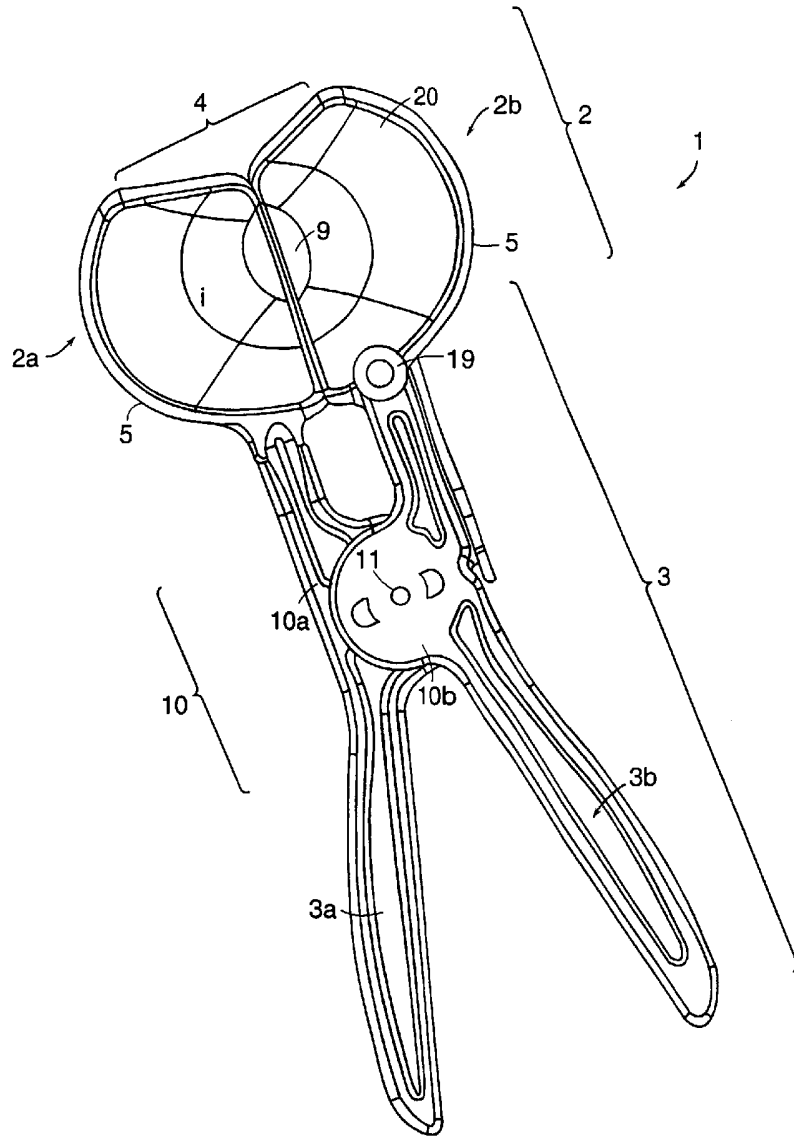


FIG. 1C

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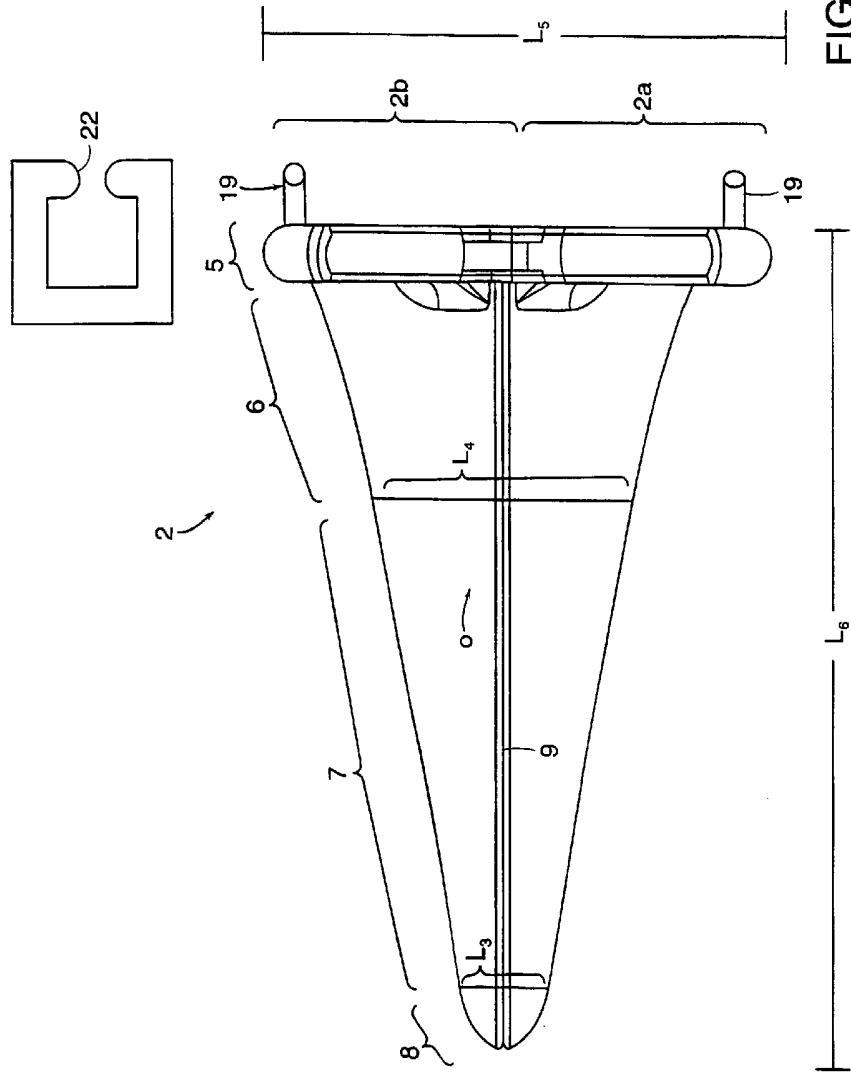


FIG. 1D

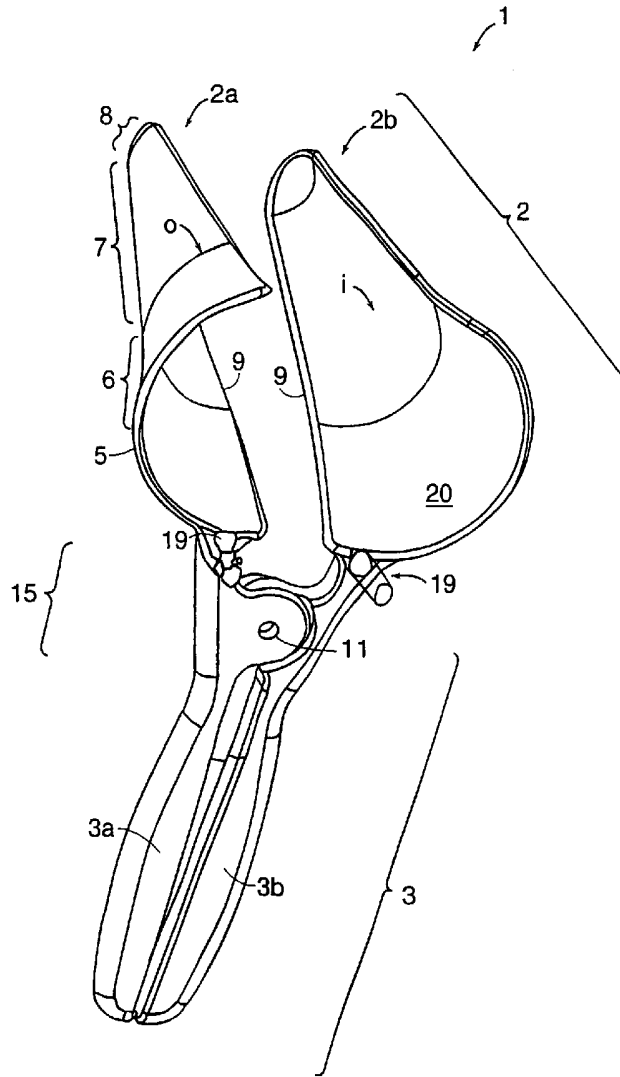


FIG. 2A

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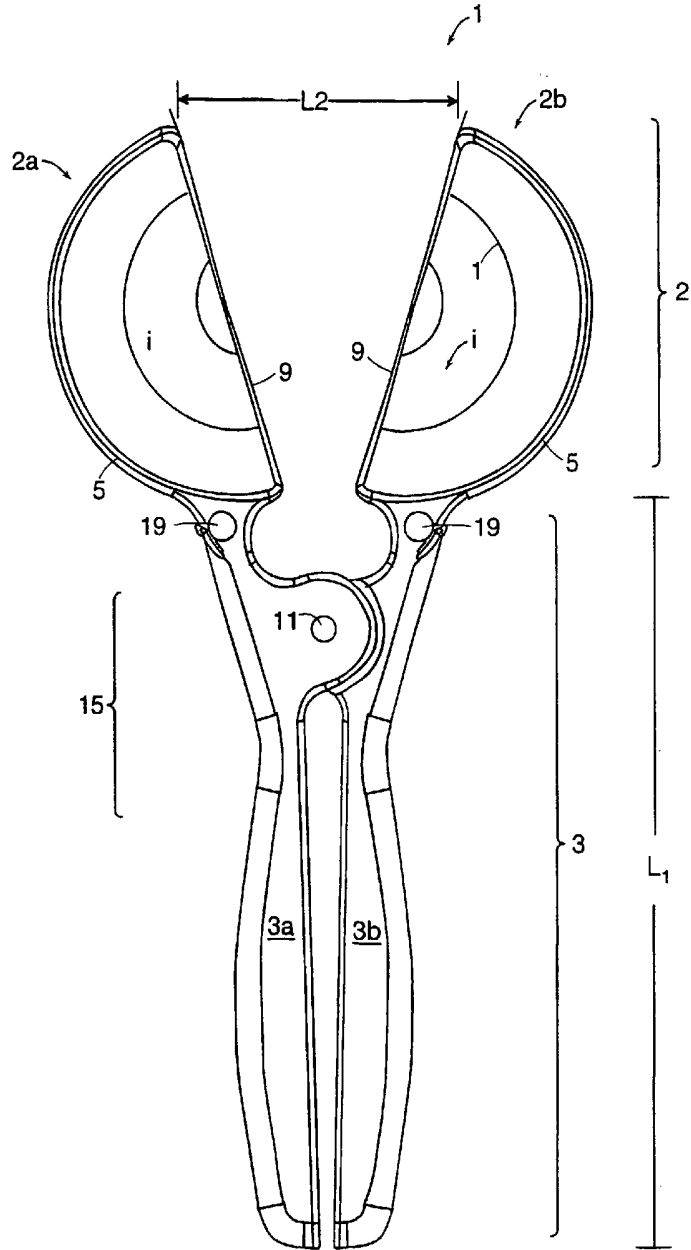


FIG. 2B

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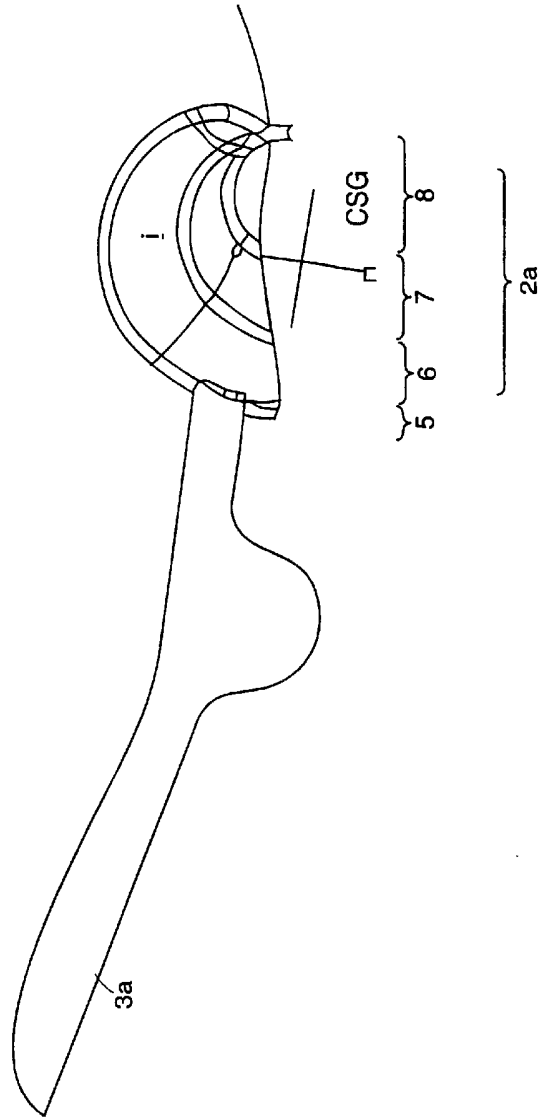


FIG. 3A

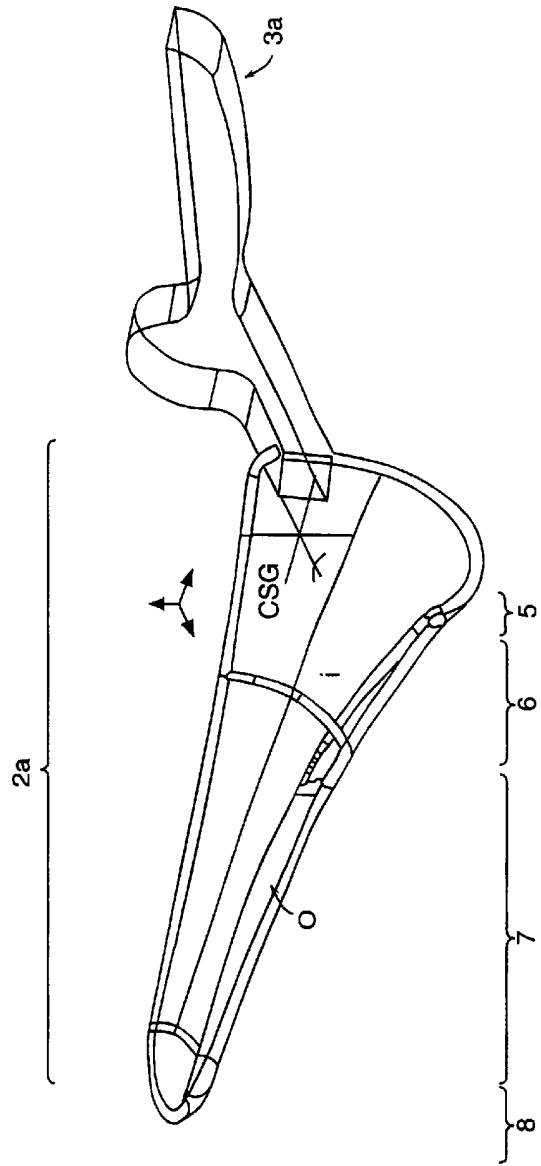


FIG. 3B

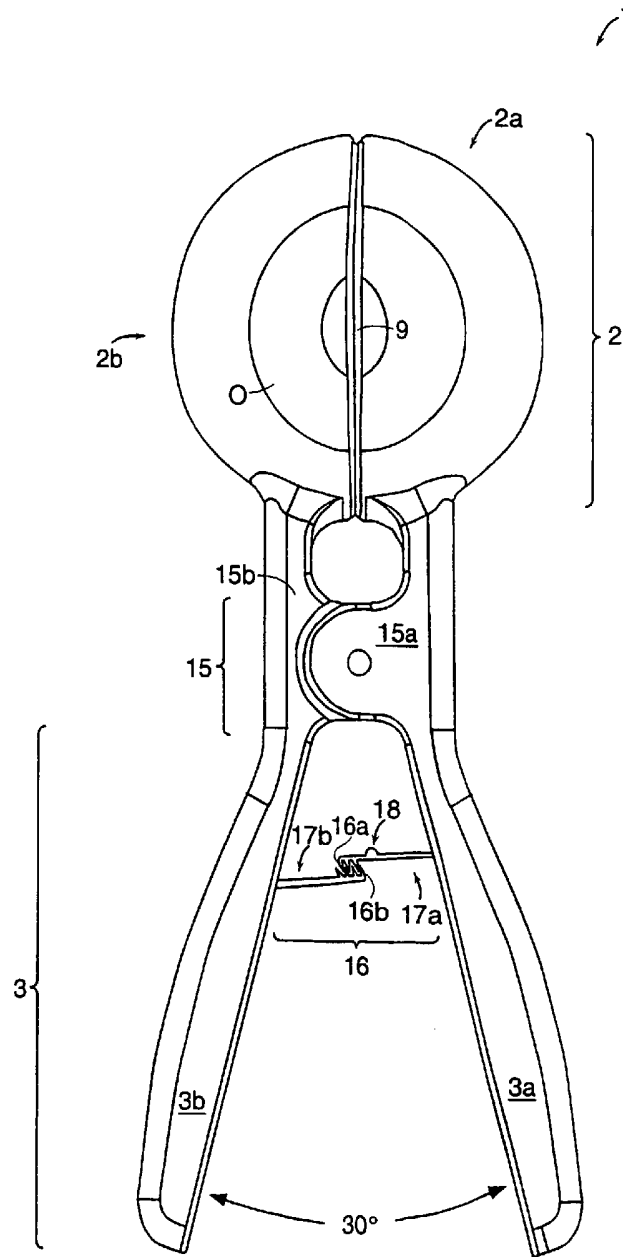


FIG. 4A

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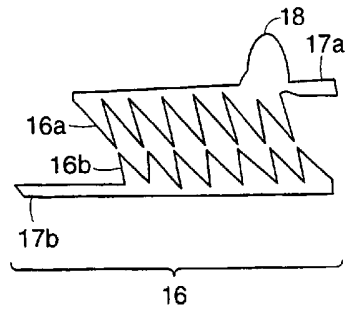


FIG. 4B

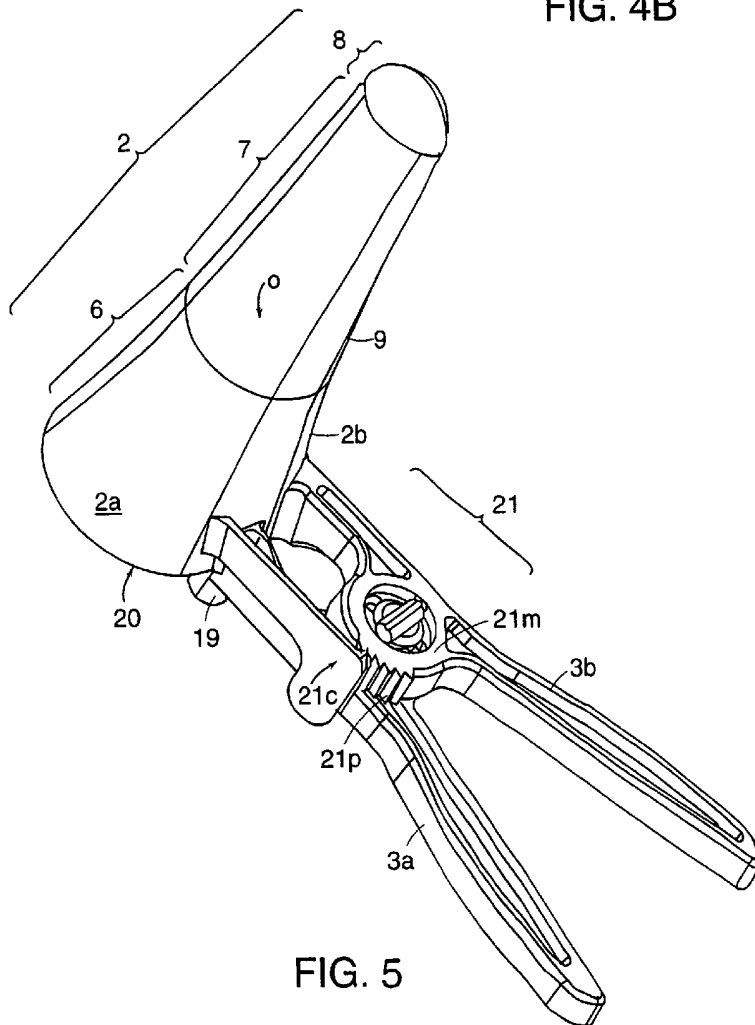


FIG. 5

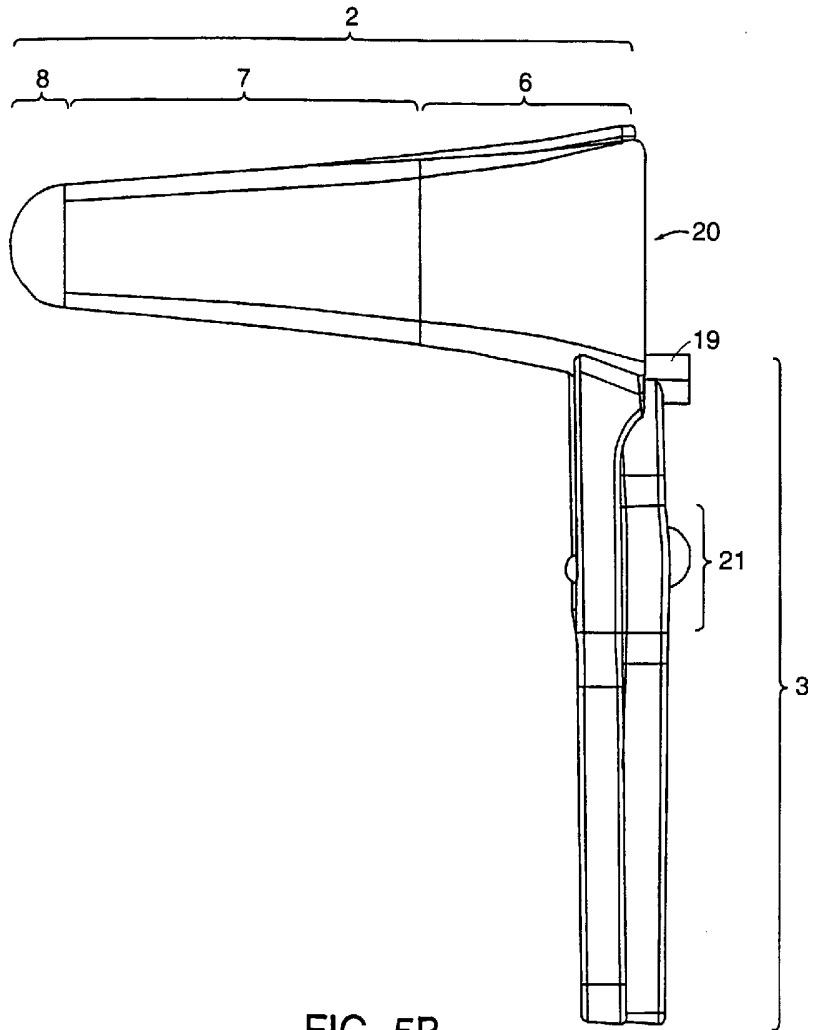


FIG. 5B

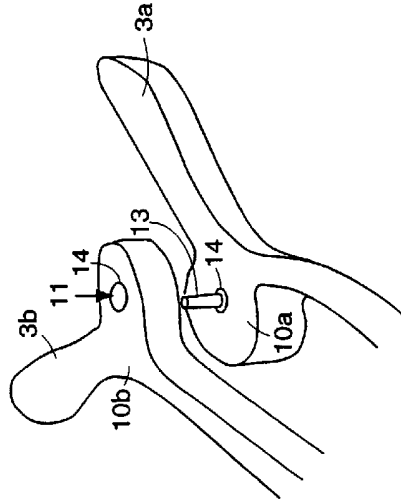


FIG. 6B

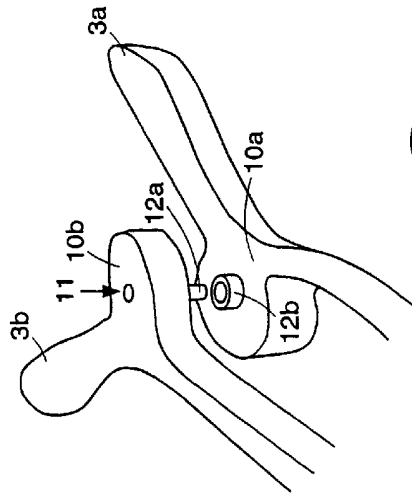


FIG. 6A

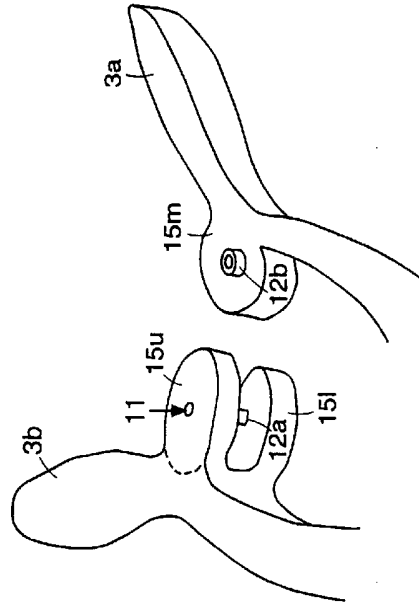


FIG. 6C

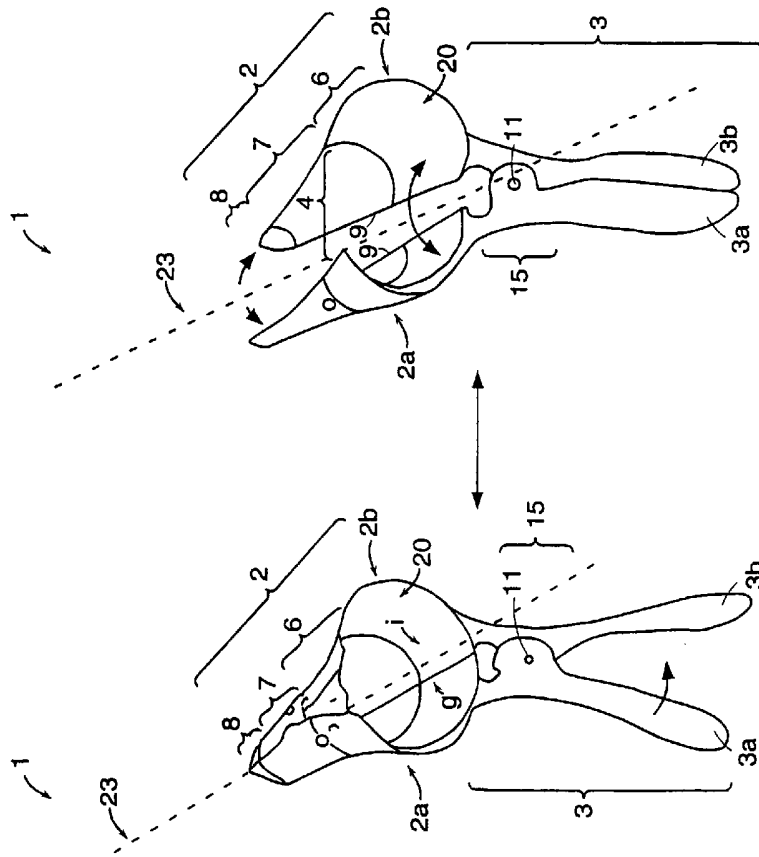


FIG 7

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